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7590 11/13/2008 Pepper Hamilton LLP			EXAMINER	
One Mellon Center			KANTAMNENI, SHOBHA	
50th Floor 500 Grant Stree	et		ART UNIT	PAPER NUMBER
Pittsburgh, PA 15219			1617	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/617.949 KIRKPATRICK ET AL. Office Action Summary Examiner Art Unit Shobha Kantamneni 1617 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 20 October 2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-4.8 and 28 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) NONE is/are allowed. 6) Claim(s) 1-4. 8. and 28 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

a) All b) Some * c) None of:

Attachment(s)	
1) Notice of References Cited (PTO-892)	4) Interview Summary (PTO-413)
Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO/Sb/08)	Paper No(s)/Mail Date 5) Notice of Informal Patent Application.
Paper No(s)/Mail Date	6) Other:

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage.

Certified copies of the priority documents have been received.

application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/20/2008 has been entered.

The Amendment received on 08/20/2008, wherein claims 1, 2 have been amended, and claim 9 has been canceled.

Applicant's arguments have been considered, but not found persuasive, the rejection of claims 1-2, 4, 8-9 under 35 U.S.C. § 103(a) as being unpatentable over Powis et al. (Anti-Cancer Drugs 1996, 7 (suppl 3), pages 121-126, PTO-1449), and in view of Halperin et al. (US 5,633,274, PTO-1449) is MAINTAINED. See under response to arguments.

Applicant's arguments have been considered, but not found persuasive, the rejection of claims 1-2, and 8-9 under 35 U.S.C. § 103(a) as being unpatentable over Oblong et al. (Cancer Chemother. Pharmacol. 1994, 34: 434-438, PTO-1449), and in view of Halperin et al. (US 5,633,274, PTO-1449) is MAINTAINED. See under response to arguments.

Applicant's arguments have been considered, but not found persuasive, the rejection of claims 1-2, 4, and 9 under 35 U.S.C. § 103(a) as being unpatentable over

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Kirkpatrick et al. (Eur. J. Med. Chem 1992, 27, pages 33-37; PTO-1449), in view of Halperin et al. (US 5,633,274, PTO-1449) is MAINTAINED. See under response to arguments.

Applicant's arguments have been considered, but not found persuasive, the rejection of claim 3 under 35 U.S.C. § 103(a) as being unpatentable over Powis et al. (Anti-Cancer Drugs 1996, 7 (suppl 3), pages 121-126, PTO-1449) or Oblong et al. (Cancer Chemother. Pharmacol. 1994, 34: 434-438, PTO-1449), and in view of Royer (US 5,783,214, PTO-892) is MAINTAINED. See under response to arguments.

The rejection of claims 1-4, 8-9, and 28 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8, 49, 52-60, 63-69, and 71 of copending Application No.10/366,751 is herein withdrawn. Note that Applicant has provided a Terminal Disclaimer.

The rejection of claims 1-4, 8-9, and 28 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-10 of copending Application No.10/600957 is herein withdrawn. Note that Applicant has provided a Terminal Disclaimer.

Claims 1-4, 8, and 28 are examined herein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, 4, 8 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Powis et al. (Anti-Cancer Drugs 1996, 7 (suppl 3), pages 121-126, PTO-1449), and in view of Halperin et al. (US 5,633,274, PTO-1449).

Powis et al. disclose compounds such as 1-methylpropyl 2-imidazolyl disulfide, and benzyl 2-imidazolyl disulfide in a pharmaceutically acceptable carrier, for the use of thioredoxin reductase inhibition. See compounds IV-2 and DLK-36, page 124 of Powis. Powis et al. teaches a composition comprising 1-methylpropyl 2-imidazolyl disulfide. It is also taught that the alkyl 2-imidazolyl compounds, 1-methylpropyl 2-imidazolyl disulfide exhibits dose-dependent antitumor activity against human MCF-7 breast cancer xenografts growing. See page 124.

Powis et al. does not teach the employment of a polymer in the composition comprising asymmetric disulfide.

Powis et al. do not teach employment of another chemotherapeutic in the composition therein.

Halperin et al. teaches that active agents that inhibit cancer cell proliferation can be administered in a variety of formulations including sustained release delivery systems containing polymer matrix. It is also taught that the sustained release delivery systems include erosional systems in which the active agent is contained in a form within a matrix. See column 6, lines 1-30. It is also taught that the agents therein which

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inhibit cancer cell proliferation can be delivered in the form of anti-cancer cocktails with other anti-cancer agents or chemotherapeutic agent. See column 6, line 64-column 7, line 25.

It would have been obvious to a person of ordinary skill in the art at the time of invention to employ 1-methylpropyl 2-imidazolyl disulfide in a polymer matrix because Halperin teaches that compounds that inhibit cancer cell proliferation can be administered in a variety of formulations which include entrapping in a polymer. One of ordinary skill in the art at the time of invention would have been motivated to employ asymmetric disulfide in a matrix comprising a polymer with the expectation of obtaining a sustained release delivery system that has the capability of releasing the active ingredient i.e. asymmetric disulfide in a controlled rate.

It would have been obvious to a person of ordinary skill in the art to employ a chemotherapeutic agent in the composition comprising asymmetric disulfide. It is generally considered *prima facia* obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by recited teachings of Powis et al. and Halperin et al. the instant claims contain two compositions used for treatment of cancer i.e. an asymmetric disulfide, and a chemotherapeutic agent. *In re Kerkohoven*, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

Furthermore, as the combined teachings of Powis et al., and Halperin et al. renders the claimed composition obvious, the property of such a claimed composition

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will also be rendered obvious by the prior art teachings, since the properties, namely "wherein said composition erodes and releases the 1-methylpropyl 2-imidazolyl disulfidein the patient for at least three hours", in claim 2, are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product.

Response to Arguments

Applicant argues that "Halperin fails to even disclose an example of an imidazole in a sustained release delivery system, and obviously fails to disclose an example of an imidazole in a sustained release delivery system that contains a polymer matrix. Accordingly without a specific teaching that asymmetric disulfides, and particularly 1-methylpropyl 2-imidazolyl disulfide, could be formulated into a sustained release delivery composition, there is no reasonable expectation of success in view of the highly unpredictable nature of the art." These arguments have been considered, but not found persuasive. Halperin et al. reference was employed for its teachings that active agents that inhibit cancer cell proliferation which include imidazoles compounds can be administered in a variety of formulations including sustained release delivery systems containing polymer matrix. Thus even though Halperin et al. does not exemplify asymmetric disulfides, it has been well-established that consideration of a reference is

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not limited to the preferred embodiments or working examples, but extends to the entire disclosure for what it fairly teaches, when viewed in light of the admitted knowledge in the art, to person of ordinary skill in the art. In re Boe, 355 F.2d 961, 148 USPQ 507, 510 (CCPA 1966); In re Lamberti, 545 F.2d 747, 750, 192 USPQ 279, 280 (CCPA 1976); In re Fracalossi, 681 F.2d 792,794,215 USPQ, 570 (CCPA 1982); In re Kaslow, 707 F.2d 1366, 1374, 217 USPQ 1089, 1095 (Fed. Cir. 1983), Powis teaches that the alkyl 2-imidazolyl compounds. 1-methylpropyl 2-imidazolyl disulfide exhibits dosedependent antitumor activity against human MCF-7 breast cancer xenografts growing. Halperin et al. teaches that anticancer agents can be administered in a variety of formulations including sustained release delivery systems containing polymer matrix. Accordingly, one of ordinary skill in the art at the time of invention would have been motivated to employ anticancer agent, asymmetric disulfide taught by Powis in a matrix comprising a polymer with the expectation of obtaining a sustained release delivery system that has the capability of releasing the active ingredient i.e. asymmetric disulfide in a controlled rate.

Applicant argues that "the unexpected nature of the results speak for themselves; that is, by sustaining the delivery of the same dose 1-methylpropyl 2-imidazolyl disulfide over a three-hour period from a 1 hour period, both the extent and duration of thioredoxin inhibition is significantly increased (even though the total amount of drug delivered is identical). It is respectfully submitted that the sustained delivery of the 1-methylpropyl 2-imidazolyl disulfide, which may be accomplished by, e.g., the inclusion of a polymer in the pharmaceutical composition, is a patentable aspect of the presently

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claimed invention." These arguments have been considered, but not found persuasive. Applicant's arguments with respect to unexpected results herein have been fully considered but are not persuasive as to the nonobviousness and/or unexpected results of the claimed invention over the prior art, since the results are not commensurate with the instant claims. Instant claims are drawn to a composition comprising an asymmetric disulfide, and a matrix which contains at least one polymer. The results provide no clear and convincing evidence of nonobviousness or unexpected results over the cited prior art because results merely demonstrate the decrease of thioredoxin employing the sustained 3 hour infusion of asymmetric disulfide, 1-methylpropyl 2- imidazolyl disulfide. The results does not demonstrate criticality of a claimed range of the compounds i.e. 1-methylpropyl 2-imidazolyl disulfide in combination with any polymer in the claimed composition. See MPEP 716.02. Therefore, the evidence presented in specification herein is not seen to be clear and convincing in support of the nonobviousness of the instant claimed invention over prior art.

Claims 1-2, 4, and 8 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Oblong et al. (Cancer Chemother. Pharmacol. 1994, 34: 434-438, PTO-1449), in view of Halperin et al. (US 5,633,274, PTO-1449).

Oblong et al. disclose compositions comprising asymmetric imidazolyl disulfides such as 1-methylpropyl 2-imidazolyl disulfide of the instant invention for the inhibition of cellular proliferation involving thioredoxin, thioredoxin reductase in an aqueous solution which is a pharmaceutical carrier. See compounds IV-2 Fig. 1. Page 435. Employment

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of this compound in 0.2 M phosphate buffer is also disclosed. See page 435, right column, bottom paragraph, lines 4-6.

Oblong et al. does not teach the employment of a polymer in the composition comprising asymmetric disulfide.

Oblong et al. do not teach employment of another chemotherapeutic.

Halperin et al. teaches that active agents that inhibit cancer cell proliferation can be administered in a variety of formulations including sustained release delivery systems containing polymer matrix. It is also taught that the sustained release delivery systems include erosional systems in which the active agent is contained in a form within a matrix. See column 6, lines 1-30. It is also taught that the agents therein which inhibit cancer cell proliferation can be delivered in the form of anti-cancer cocktails with other anti-cancer agents or chemotherapeutic agent. See column 6, line 64-column 7, line 25.

It would have been obvious to a person of ordinary skill in the art at the time of invention to employ 1-methylpropyl 2-imidazolyl disulfide, an agent that inhibits cell proliferation according to Oblong et al. in a polymer matrix because Halperin teaches that compounds that inhibit cancer cell proliferation can be administered in a variety of formulations which include entrapping in a polymer. One of ordinary skill in the art at the time of invention would have been motivated to employ asymmetric disulfide in a matrix comprising a polymer with the expectation of obtaining a sustained release delivery system that has the capability of releasing the active ingredient i.e. asymmetric disulfide in a controlled rate.

It would have been obvious to a person of ordinary skill in the art to employ a chemotherapeutic agent in the composition comprising asymmetric disulfide. It is generally considered *prima facia* obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by recited teachings of Oblong et al. and Halperin et al. the instant claims contain two compositions used for treatment of cancer i.e. an asymmetric disulfide, and a chemotherapeutic agent. *In re Kerkohoven*, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

Furthermore, as the combined teachings of Oblong et al., and Halperin et al. renders the claimed composition obvious, the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties, namely "wherein said composition erodes and releases the 1-methylpropyl 2-imidazolyl disulfidein the patient for at least three hours", in claim 2, are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product.

Response to Arguments

Applicant's arguments have been considered, but not found persuasive for reasons as set forth above (See under Response to Arguments, for Powis et al. rejection).

Claims 3, and 28 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Powis et al. (Anti-Cancer Drugs 1996, 7 (suppl 3), pages 121-126, PTO-1449) or Oblong et al. (Cancer Chemother. Pharmacol. 1994, 34: 434-438, PTO-1449), and in view of Royer (US 5,783,214, PTO-892).

Powis et al., and Oblong et al. are applied as discussed in the above rejection.

Powis et al. or Oblong et al. do not teach the employment of a hydrophilic polymer in the composition comprising asymmetric disulfide.

Royer teaches sustained release delivery system comprising a gel matrix comprising hydrophilic polymer, gelatin for drugs which include anticancer drugs. It is taught that the delivery system therein provides easy control of release profile for drugs. See column 9, lines 16-20.

It would have been obvious to a person of ordinary skill in the art at the time of invention to employ 1-methylpropyl 2-imidazolyl disulfide, an agent that inhibits cell proliferation according to Powis et al. or Oblong et al. in a hydrophilic polymer matrix, gelatin because Royer teaches that anticancer drugs are incorporated into gel matrix which contains gelatin. One of ordinary skill in the art at the time of invention would have been motivated to employ asymmetric disulfide in a gel matrix comprising a

hydrophilic polymer, gelatin with the expectation of obtaining a sustained release delivery system that has the capability of releasing the asymmetric disulfide in a controlled rate.

Response to Arguments

Applicant's arguments have been considered, but not found persuasive, as discussed above, and those found below.

Applicant argues that "as noted by Royer, delivery systems of medicinal agents is a challenge because, among other things, the medicinal may be chemically modified during formulation. The delivery systems of Rover are specifically designed for the delivery of proteins, and there is no teaching or suggestion that the delivery of proteins using the systems of Royer could be applied to 1-methylpropyl 2-imidazolyl disulfide". Applicant's arguments have been considered, but not found persuasive. Powis teaches that the alkyl 2-imidazolyl compounds, 1-methylpropyl 2-imidazolyl disulfide exhibits antitumor activity against human MCF-7 breast cancer xenografts growing. Rover teaches sustained release delivery system comprising a gel matrix comprising hydrophilic polymer, gelatin for drugs which include anticancer drugs. Thus even though Royer does not exemplify asymmetric disulfides as anticancer drugs employed therein, it has been well-established that consideration of a reference is not limited to the preferred embodiments or working examples, but extends to the entire disclosure for what it fairly teaches, when viewed in light of the admitted knowledge in the art, to person of ordinary skill in the art. In re Boe, 355 F.2d 961, 148 USPQ 507, 510 (CCPA 1966); In re Lamberti, 545 F.2d 747, 750, 192 USPQ 279, 280 (CCPA 1976); In re

Fracalossi, 681 F.2d 792, 794, 215 USPQ, 570 (CCPA 1982); In re Kaslow, 707 F.2d 1366, 1374, 217 USPQ 1089, 1095 (Fed. Cir. 1983). From the teachings of Royer, one of ordinary skill in the art at the time of invention would have been motivated to employ anticancer agent, 1-methylpropyl 2-imidazolyl disulfide in a gel matrix comprising a hydrophilic polymer, gelatin with the expectation of obtaining a sustained release delivery system that has the capability of releasing the anticancer agent, asymmetric disulfide in a controlled rate, since Royer broadly teaches that anticancer drugs are incorporated into gel matrix which contains gelatin for easy control of release profile for anticancer drugs.

Further, as discussed above applicant's results provide no clear and convincing evidence of nonobviousness or unexpected results over the cited prior art because results merely demonstrate the decrease of thioredoxin employing the sustained 3 hour infusion of asymmetric disulfide, 1-methylpropyl 2- imidazolyl disulfide. The results does not demonstrate criticality of a claimed range of the compounds i.e. 1-methylpropyl 2-imidazolyl disulfide in combination with any polymer in the claimed composition. See MPEP 716.02. Therefore, the evidence presented in specification herein is not seen to be clear and convincing in support of the nonobviousness of the instant claimed invention over prior art.

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Claims 1-2, 4 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kirkpatrick et al. (Eur. J. Med. Chem 1992, 27, pages 33-37; PTO-1449), in view of Halperin et al. (US 5,633,274, PTO-1449).

Kirkpatrick et al. disclose compounds 1-methylpropyl 2-imidazolyl disulfide (IV-2) of the instant invention for the evaluation of selective cytotoxicity to hypoxic EMT6 tumor cells. See compounds 11, Table II. Page 34; page 35, right column, lines 1-3. Employment of this compound in 75 mL of 0.05 potassium phosphate buffer containing 0.1 M KCl is also disclosed. See page 37, left column, 2nd para from bottom.

Kirkpatrick et al. does not teach the employment of a polymer in the composition comprising disulfide.

Halperin et al. teaches that active agents that inhibit cancer cell proliferation can be administered in a variety of formulations including sustained release delivery systems containing polymer matrix. It is also taught that the sustained release delivery systems include erosional systems in which the active agent is contained in a form within a matrix. See column 6, lines 1-30. It is also taught that the agents therein which inhibit cancer cell proliferation can be delivered in the form of anti-cancer cocktails with other anti-cancer agents or chemotherapeutic agent. See column 6, line 64-column 7, line 25.

It would have been obvious to a person of ordinary skill in the art at the time of invention to employ 1-methylpropyl 2-imidazolyl disulfide in a polymer matrix because Halperin teaches that compounds that inhibit cancer cell proliferation can be administered in a variety of formulations which include entrapping in a polymer. One of

ordinary skill in the art at the time of invention would have been motivated to employ asymmetric disulfide in a matrix comprising a polymer with the expectation of obtaining a sustained release delivery system that has the capability of releasing the active ingredient i.e. asymmetric disulfide in a controlled rate.

Furthermore, as the combined teachings of Kirkpatrick et al., and Halperin et al. renders the claimed composition obvious, the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties, namely "wherein said composition erodes and releases the 1-methylpropyl 2-imidazolyl disulfidein the patient for at least three hours", in claim 2, are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product.

Response to Arguments

Applicant's arguments have been considered, but not found persuasive for reasons as set forth above (See under Response to Arguments, for Powis et al. rejection).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Friday, 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, Ph.D can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shobha Kantamneni, Ph.D Patent Examiner Art Unit: 1617

/Shengjun Wang/ Primary Examiner, Art Unit 1617 Application Number

 Application/Control No.
 Applicant(s)/Patent under Reexamination

 10/617,949
 KIRKPATRICK ET AL.

 Examiner
 Art Unit

 Shobha Kantamneni
 1617